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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,081	11/16/2000	Joaquin Villalobos	CRD-726	5133

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/714,081

Applicant(s)

VILLALOBOS ET AL. *On*

Examiner

Cheryl L. Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 06 August 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Drawings

1. The corrected or substitute drawings were received on August 6, 2002. These drawings are approved.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is in a format reciting a combination-subcombination. The combination being the delivery apparatus, and the subcombination being the stent. The scope differs within the claim, wherein the scope of the preamble is a delivery apparatus and the scope of the body claim part c is a stent structure. Patentable weight will not be given to stent structure unless the preamble scope is changed to for example --a system-- or --an apparatus--.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen (USPN-5,324,304, cited in previous office action) in view of Johnson et al. (USPN 6,136,006, cited in previous office action). Referring to claims 1 and 4, Rasmussen discloses a delivery apparatus comprising an outer sheath (5), an inner shaft (8, 10) coaxially and slidably within the sheath (5), wherein

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the inner shaft (8) further comprises at least two grooves (14), and a self-expanding stent (1; col.1, lines 5-10) having at least two legs (2) attached to the proximal end of the stent, extending proximally, each leg having a flange (4), wherein flanges (4) are set within grooves (14) releasably attaching the stent (1) to the shaft (8, 10). Rasmussen does not disclose however, a removable member attached to the inner shaft. Johnson teaches a delivery apparatus for a self-expanding stent having a removable member (76) on the exterior surface of an inner shaft (26) in order to prevent premature deployment of the stent and prevent movement of the inner catheter relative to the outer sheath, increasing safety (col.6, lines 61-67; col.7, lines 1-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Johnson's teaching of use of a removable member on an inner shaft of a delivery apparatus, with the delivery apparatus of Rasmussen in order to increase safety by preventing premature deployment of the stent and prevent movement of the inner catheter relative to the outer sheath.

Referring to claims 2, 3, 12, and 13, Johnson teaches a removable member (76) that is semi-cylindrical and snap fits over the inner shaft (26), (fig.1 with member, fig.5 without member), (longitudinal slit for snap fit, col.7, lines 1-3) the removable member having a diameter larger than the diameter to the inner shaft in order to prevent movement of the inner catheter relative to the outer sheath prior to deployment and to provide a means for removal upon deployment of the stent (col.6, lines 61-67; col.7, lines 1-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Johnson's sized snap fit removable member on a delivery apparatus with Rasmussen's delivery apparatus in order to prevent movement of the inner catheter relative to the outer sheath prior to deployment and to provide a means for removal upon deployment of the stent.

Referring to claim 7, Rasmussen discloses flanges (4) that fit completely within the grooves (14), (col.2, lines 30-32; col.4, lines 29-34; col.5, lines 49-54).

Referring to claims 8 and 10, Rasmussen discloses legs that are equally spaced apart and extend distally and axially away from the self-expanding stent (fig.4, 6, 8).

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Referring to claims 6, 9, and 11, Rasmussen discloses legs having bent L-shaped flanges and line slit grooves in the inner shaft. Rasmussen does not disclose expressly I or T shaped flanges or grooves. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to create an I or T shaped groove/flange because Applicant has not disclosed that an I or T shaped flange or groove provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with L shaped flanges/grooves because any flange will fit within a corresponding groove providing a low profile diameter, regardless the shape of the flange/groove. Therefore, it would have been an obvious matter of design choice to modify Rasmussen to obtain the invention as specified in claims 6, 9, and 11.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen in view of Johnson as applied to claim 4 above, and further in view of Aiba et al. (USPN 6,221,096 B1, cited in previous office action). Rasmussen discloses a self-expanding stent, however does not explicitly disclose the material the stent is made of. Aiba teaches use of a superelastic nickel titanium material for a self-expanding stent (col.2, lines 28-30, 65-67) in order to provide an increased elasticity compared to other metals (col.3, lines 1-13; col.4, lines 30-41) thereby providing an easy, safe delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Rasmussen in view of Johnson's self-expanding stent with Aiba's material choice for self-expanding stents in order to provide increased elasticity compared to other metals, providing an easy safe delivery.

Response to Arguments

6. Applicant's arguments filed August 6, 2002 have been fully considered but they are not persuasive. The examiners position is believed to be adequately described in the rejection above.

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Conclusion

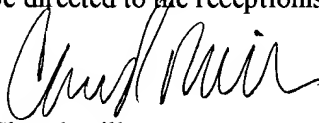
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Cheryl Miller

October 30, 2002


BRUCE SNOW
PRIMARY EXAMINER